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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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VENABLE LLP				
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WASHINGTON, DC 20043-9998				
EXAMINER				
ROYDS, LESLIE A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/735,910

Applicant(s)

HUANG ET AL.

Examiner

Leslie A. Royds

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 10, 15, 18-20 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-10, 15, 18-20 and 32-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 9-10, 15, 18-20 and 32-37 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and submission filed August 18, 2008 to enter the after-final submission dated June 25, 2008 has been received and entered into the present application. Accordingly, prosecution has been reopened.

Applicant is reminded of the election of species of M4N (tetra-O-methylnordihydroguaiaretic acid; also known as meso-1,4-bis(3,4-dimethoxyphenyl)-(2R,3S)-dimethylbutane) in the reply filed August 21, 2006 in response to the requirement for restriction/election dated June 20, 2006. Accordingly, claims 9-10, 15, 18-20 and 32-33 remain under examination as they are explicitly directed to the subject matter that was elected and previously under examination and newly added claims 34-37 are withdrawn from consideration pursuant to 37 C.F.R. 1.142(b) as being directed to non-elected subject matter (i.e., compounds wherein R1-R4 are identical and are a substituted or unsubstituted amino acid residue).

Claims 9-10, 15, 18-20 and 32-37 are pending. Claims 22-31 are cancelled. Claim 9 is amended. Claims 34-37 are newly added. Claims 9-10, 15, 18-20 and 32-33 are under examination and claims 34-37 are withdrawn from consideration pursuant to 37 C.F.R. 1.142(b) as being directed to non-elected subject matter.

Applicant's arguments, filed June 25, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-10, 15 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Howell et al. (U.S. Patent No. 5,541,232; 1996), already of record, for the reasons of record set forth at p.2-6 of the previous Office Action dated March 25, 2008, of which said reasons are herein incorporated by reference.

Newly amended claim 9 remains properly rejected in the instant rejection because Howell et al. teaches a method for the inhibition and/or reversal of multidrug resistant phenomenon in a patient and thereby treatment of both solid malignant tumors and hematological malignancies comprising the administration of NDGA (*meso*-1,4-bis(3,4-dihydroxyphenyl)-2,3-dimethylbutane; col.4, 1.33-34) or an analogue thereof (abstract and col.5, 1.22-41), such as, e.g., the *meso* isomer of 1,4-bis(3,4-dimethoxyphenyl)-2,3-dimethylbutane (col.6, 1.3-7 and col.16, 1.18-col.17, 1.9), to said patient, wherein the hematologic malignancy is, e.g., childhood leukemia, acute or chronic leukemia (col.6, 1.35-40 and col.16, 1.18-col.17, 1.9), and further wherein the catecholic butane may be formulated in combination with a pharmaceutically acceptable additives or adjuvants (col.15, 1.49-59), such as, e.g., penetration enhancers, such as dimethylsulfoxide (col.7, 1.3-15), and may be applied topically, orally or parenterally to the treatment site (col.6, 1.52-53). Howell et al. discloses the treatment of mammals, including humans (col.6, 1.39-40).

The elected compound tetra-O-methylnordihydroguaiaretic acid is also known as the *meso* isomer of 1,4-bis(3,4-dimethoxyphenyl)-(2R,3S)-dimethylbutane (please see Figure 1 of the instant drawings), which corresponds directly to the chemical compound of Howell et al. Please also reference Howell et al. at col.6, 1.3-17, where the reference further discloses all stereoisomeric configurations of the disclosed

compound 1,4-bis(3,4-dimethoxyphenyl)-dimethylbutane, which anticipates the presently claimed limitation of the (2R,3S) configuration of the elected species.

Though Applicant amended the overall transitional language of the instant claims from “comprising” to “consisting essentially of” and also limited the composition to be administered from “comprising an effective amount of a compound of” the formula set forth in instant claim 9 to “consisting essentially of an effective amount of” the compound set forth in instant claim 9, Howell et al. still applies as prior art over the instant claims because the disclosed method for treating hematological malignancies, such as, e.g., childhood leukemia, acute or chronic leukemia (col.6, 1.35-40 and col.16, 1.18-col.17, 1.9), administers the NDGA compound in combination with a pharmaceutically acceptable additive or adjuvant (abstract; col.5, 1.22-41; col.15, 1.49-49) to the patient in need of treatment of a hematological malignancy. The reference clearly provides for an embodiment wherein NDGA is administered to a patient to treat a solid tumor or hematological malignancy (i.e., in this case, leukemia) in the absence of the administration of any other elements and/or the execution of any other steps to achieve the disclosed therapeutic objective and, therefore, meets the “consisting essentially of” language as recited in the instant claims. Please see, e.g., col.5, 1.10-41.

Though Applicant argues that the disclosure of Howell et al. inherently requires the administration of an additional agent to which the multi-drug resistance develops, note that Howell et al. clearly provides for the treatment of neoplastic diseases “that may fail to respond to chemotherapeutic agents *de novo* or that may become resistant to treatment after an initial response” and explicitly states that the disclosed method is applicable to neoplastic cells that have developed or are susceptible to developing drug resistance or multidrug resistance, of which childhood leukemia and chronic leukemia are each named as hematological malignancies that *can* develop multidrug resistance. Please see Howell et al., col.6, 1.25-40 and 45-51. In other words, Howell et al. provides for the treatment of neoplastic conditions (i.e., childhood leukemia, chronic leukemia, etc.) that are *not multi-drug resistant at the time of*

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treatment, but have the *potential* to become multi-drug resistant. Accordingly, the disclosure of Howell et al. explicitly provides for an embodiment wherein the neoplastic condition is *not* multi-drug resistant at the time of treatment with NDGA and, therefore, has *not* been inherently treated with another chemotherapeutic agent to which multi-drug resistance has developed. As a result, there is absolutely no requirement, explicit or implicit, for this disclosed embodiment in Howell et al. that an additional drug is administered, which supports the conclusion presented *supra* that, because Howell et al. clearly provides for the administration of NDGA in the absence of any additional elements, the disclosure still clearly applies as anticipatory prior art over the instant claims, despite Applicant's amendment to the transitional language (i.e., from "comprising" to "consisting essentially of") of the instant claims.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Howell et al. is directed to the use of catecholic butanes such as NDGA for the treatment of multidrug resistance, which differs from Applicant's claimed use in that the reference inherently requires the administration of additional drug(s) to which the multidrug resistance develops. Applicant alleges that the amendment to claim 9 (i.e., to now recite "consisting essentially of") excludes the use of such additional drugs.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

As described in detail *supra*, Howell et al. clearly provides for the treatment of neoplastic diseases "that may fail to respond to chemotherapeutic agents *de novo* or that may become resistant to treatment after an initial response" and explicitly states that the disclosed method is applicable to neoplastic cells that have developed or are susceptible to developing drug resistance or multidrug resistance, of which childhood leukemia and chronic leukemia are each named as hematological malignancies that *can* develop multidrug resistance. Please see Howell et al., col.6, l.25-40 and 45-51. In other words, Howell et al. provides for the treatment of neoplastic conditions (i.e., childhood leukemia,

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chronic leukemia, etc.) that are *not multi-drug resistant at the time of treatment*, but have the *potential* to become multi-drug resistant. Accordingly, the disclosure of Howell et al. explicitly provides for an embodiment wherein the neoplastic condition is *not* multi-drug resistant at the time of treatment and, therefore, has *not* been inherently treated with another chemotherapeutic agent to which multi-drug resistance has developed. As a result, there is absolutely no requirement, explicit or implicit, in this disclosed embodiment of Howell et al. that an additional drug is administered, which supports the conclusion presented *supra* that, because Howell et al. clearly provides for the administration of NDGA in the absence of any additional elements, the disclosure still clearly applies as anticipatory prior art over the instant claims, despite Applicant's amendment to the transitional language (i.e., from "comprising" to "consisting essentially of") of the instant claims.

Even if, *arguendo*, Howell et al. limited his teaching only to neoplastic conditions that were multi-drug resistant and, thus, were inherently treated previously with additional drug(s) that had caused the multi-drug resistance (which the Examiner does not concede), Applicant is reminded that the instant claims fail to recite *any* exclusion whatsoever as to what *previous* therapy may have been administered prior to administration of the NDGA therapy as instantly claimed. The instant claims as presently written solely exclude the *concomitant* administration of additional elements and/or the *concomitant* execution of additional steps *that do not affect the basic and novel characteristics of the invention*, but provide absolutely no limitation on whether the patient received any prior agent(s) for the treatment of their neoplastic condition prior to initiating the method of treatment as instantly claimed. By Applicant's own admission (p.5-6, Remarks), the alleged "additional drugs" to which the multi-drug resistance develops must have been administered prior to the NDGA compound in order to render the neoplastic condition multi-drug resistant. However, Applicant's claims as presently written fail to patentably exclude the prior administration of additional drugs to which the multi-drug resistance develops. In this case, Applicant would again be attempting to argue patentable distinction over features that are not claimed. Applicant is

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reminded that, though the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Please see *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For these reasons, and those previously made of record at p.2-6 of the Office Action dated March 25, 2008, rejection of claims 9-10, 15 and 18-20 is proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-10, 15, 18-20 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howell et al. (U.S. Patent No. 5,541,232; 1996), already of record, for the reasons of record set forth at pages 6-10 of the previous Office Action dated March 25, 2008, of which said reasons are herein incorporated by reference.

Newly amended claim 9 remains properly rejected in the instant rejection because Howell et al. teaches a method for the inhibition and/or reversal of multidrug resistant phenomenon in a patient and

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thereby treatment of both solid malignant tumors and hematological malignancies comprising the administration of NDGA (*meso*-1,4-bis(3,4-dihydroxyphenyl)-2,3-dimethylbutane; col.4, 1.33-34) or an analogue thereof (abstract and col.5, 1.22-41), such as, e.g., the *meso* isomer of 1,4-bis(3,4-dimethoxyphenyl)-2,3-dimethylbutane (col.6, 1.3-7 and col.16, 1.18-col.17, 1.9), to said patient, wherein the hematologic malignancy is, e.g., childhood leukemia, acute or chronic leukemia (col.6, 1.35-40 and col.16, 1.18-col.17, 1.9), and further wherein the catecholic butane may be formulated in combination with a pharmaceutically acceptable additives or adjuvants (col.15, 1.49-59), such as, e.g., penetration enhancers, such as dimethylsulfoxide (col.7, 1.3-15), and may be applied topically, orally or parenterally to the treatment site (col.6, 1.52-53). Howell et al. discloses the treatment of mammals, including humans (col.6, 1.39-40).

The elected compound tetra-O-methylnordihydroguaiaretic acid is also known as the *meso* isomer of 1,4-bis(3,4-dimethoxyphenyl)-(2*R*,3*S*)-dimethylbutane (please see Figure 1 of the instant drawings), which corresponds directly to the chemical compound of Howell et al. Please also reference Howell et al. at col.6, 1.3-17, where the reference further discloses all stereoisomeric configurations of the disclosed compound 1,4-bis(3,4-dimethoxyphenyl)-dimethylbutane, which renders obvious the presently claimed limitation of the (2*R*,3*S*) configuration of the elected species.

Though Applicant amended the overall transitional language of the instant claims from "comprising" to "consisting essentially of" and also limited the composition to be administered from "comprising an effective amount of a compound of" the formula set forth in instant claim 9 to "consisting essentially of an effective amount of" the compound set forth in instant claim 9, Howell et al. still applies as prior art over the instant claims because the disclosed method for treating hematological malignancies, such as, e.g., childhood leukemia, acute or chronic leukemia (col.6, 1.35-40 and col.16, 1.18-col.17, 1.9), administers the NDGA compound in combination with a pharmaceutically acceptable additive or adjuvant (abstract; col.5, 1.22-41; col.15, 1.49-49) to the patient in need of treatment of a hematological

malignancy. The reference clearly provides for an embodiment wherein NDGA is administered to a patient to treat a solid tumor or hematological malignancy (i.e., in this case, leukemia) in the absence of the administration of any other elements and/or the execution of any other steps to achieve the disclosed therapeutic objective and, therefore, meets the “consisting essentially of” language as recited in the instant claims. Please see, e.g., col.5, l.10-41.

Though Applicant argues that the disclosure of Howell et al. inherently requires the administration of an additional agent to which the multi-drug resistance develops, note that Howell et al. clearly provides for the treatment of neoplastic diseases “that may fail to respond to chemotherapeutic agents *de novo* or that may become resistant to treatment after an initial response” and explicitly states that the disclosed method is applicable to neoplastic cells that have developed or are susceptible to developing drug resistance or multidrug resistance, of which childhood leukemia and chronic leukemia are each named as hematological malignancies that *can* develop multidrug resistance. Please see Howell et al., col.6, l.25-40 and 45-51. In other words, Howell et al. provides for the treatment of neoplastic conditions (i.e., childhood leukemia, chronic leukemia, etc.) that are *not multi-drug resistant at the time of treatment*, but have the *potential* to become multi-drug resistant. Accordingly, the disclosure of Howell et al. explicitly provides for an embodiment wherein the neoplastic condition is *not* multi-drug resistant at the time of treatment and, therefore, has *not* been inherently treated with another chemotherapeutic agent to which multi-drug resistance has developed. As a result, there is absolutely no requirement, explicit or implicit, in this disclosed embodiment of Howell et al. that an additional drug is administered, which supports the conclusion presented *supra* that, because Howell et al. clearly provides for the administration of NDGA in the absence of any additional elements, the disclosure still clearly applies as prior art over the instant claims, despite Applicant's amendment to the transitional language (i.e., from “comprising” to “consisting essentially of”) of the instant claims.

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Even if, *arguendo*, Howell et al. limited his teaching only to neoplastic conditions that were multi-drug resistant and, thus, were inherently treated previously with additional drug(s) that had caused the multi-drug resistance, Applicant is reminded that the instant claims fail to recite *any* exclusion whatsoever as to what *previous* therapy may have been administered prior to administration of the NDGA therapy as instantly claimed. The instant claims as presently written solely exclude the *concomitant* administration of additional elements and/or the *concomitant* execution of additional steps *that do not affect the basic and novel characteristics of the invention*, but provide absolutely no limitation on whether the patient received any prior agent(s) for the treatment of their neoplastic condition prior to initiating the method of treatment as instantly claimed. By Applicant's own admission (p.5-6, Remarks), the alleged "additional drugs" to which the multi-drug resistance develops must have been administered prior to the NDGA compound in order to render the neoplastic condition multi-drug resistant. However, Applicant's claims as presently written fail to patentably exclude the prior administration of additional drugs to which the multi-drug resistance develops. In this case, Applicant would again be attempting to argue patentable distinction over features that are not claimed. Applicant is reminded that, though the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Please see *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For these reasons, and those previously made of record at pages 6-10 of the Office Action dated March 25, 2008, rejection of claims 9-10, 15, 18-20 and 32-33 is proper.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual

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or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-10, 15, 18-20 and 32-33 remain provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 21, 24-26, 30-32, 35, 39-50, 54-62 and 64-72 of U.S. Patent Application No. 11/284,111, already of record, for the reasons of record set forth at page 10 of the previous Office Action dated March 25, 2008, of which said reasons are herein incorporated by reference.

Applicant requests to defer filing a Terminal Disclaimer until allowable subject matter has been indicated.

In view of the fact that allowable subject matter has not yet been identified in the instant case, and further in view of the fact that Applicant has failed to file a Terminal Disclaimer over the cited copending application(s) and also that Applicant has failed to present any arguments or remarks directed to the propriety of the rejection set forth *supra*, the provisional rejection made under the judicially created doctrine of obviousness-type double patenting remains proper and is **maintained**.

Conclusion

Rejection of claims 9-10, 15, 18-20 and 32-33 is proper.

Claims 34-37 are **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

September 27, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614